

REMARKS

1. The Amendments and the Support Therefor

Thirty-five claims (17, 22-25, 27-39, 41-49, 52-57, and 76-77) have been canceled, no new claims have been added, and claim 1 has been amended to leave claims 1-6, 8-16, 18-21, 58, and 60-77 in the application. No new matter has been added by the amendments, wherein claim 1 is amended to incorporate claim 17.

2. Election/Restriction

Withdrawn claims 22-25, 27-39, 41-49, and 52-57 have been canceled without prejudice toward pursuit of these claims in one or more divisional or continuing applications.

3. Rejection of Claims 1, 2, 5, 6, 8-15, 17-21, 58, 60, 62, and 64-71 under 35 USC §103(a) in view of U.S. Patent 5,643,195 to Drevet et al. and U.S. Patent 6,565,525 to Burbank et al.

Before discussing the rejections, it is initially useful to review the cited references.

U.S. Patent 5,643,195 to *Drevet* shows a shunt in FIG. 1 (reproduced below) including an inlet port 3 opening onto a fluid passageway 11, with the fluid passageway 11 extending between an upstream side 6 and a downstream side 13, and with the downstream side 13 opening onto an outlet 5 (column 4 lines 46-63). A valve 14 having a piston head is situated between the upstream side 6 and the downstream side 13 (column 4 line 64-column 5 line 1). The piston head is biased to close the fluid passageway 11 by a deformable diaphragm 7 on which the piston 14 rides (column 4 lines 50-52 and 63-65), with one side 12 of the diaphragm 7 being a closed chamber at ambient pressure (column 4 lines 54-56). The piston head is also biased by a leaf spring 17 bearing against a tail end 19 of the piston, wherein the location of the leaf spring 17 (and thus its pressure on the piston) is adjustable via a screw 18 (column 5 lines 10-17). As fluid flows into the upstream side 6 via inlet port 3, if the pressure sufficiently rises in the upstream side 6 to urge the diaphragm 7 and piston 14 downwardly against the spring 17, the piston 14 will open the fluid passageway 11 and allow flow to the downstream side 13 and outlet 5 (column 5 line 24 onward).

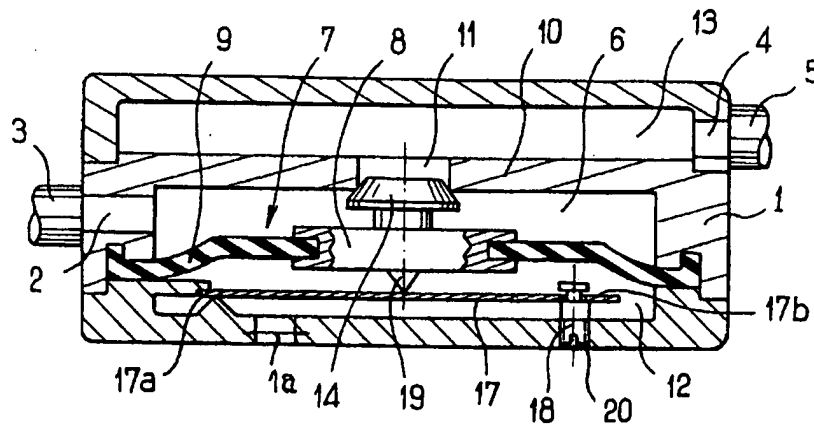
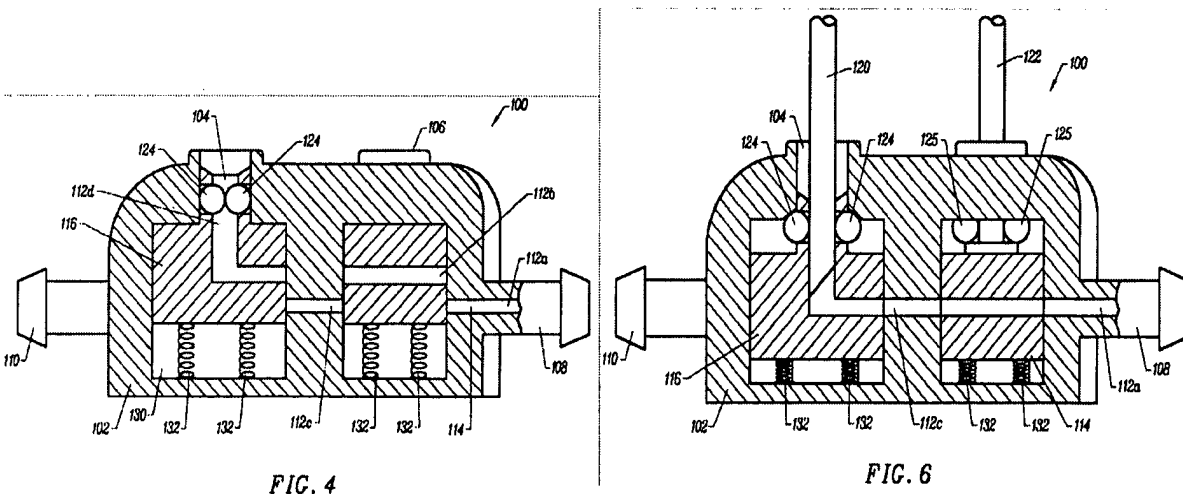


FIG. 1

U.S. Patent 6,565,525 to *Burbank et al.* illustrates a valve port arrangement for use in hemodialysis, wherein blood is taken ("accessed") from a patient at the same time it is also returned. The valve port arrangement is intended to halt all blood flow in the event needles leading to one or more of the blood access port and/or the blood return port are dislodged from the patient (column 2 lines 9-28, 57-67). Looking to FIGS. 4-6, connector 108 is intended to be connected to a vein or the like for access (or return) (column 7 lines 12-17), and connector 110 is then intended to be connected to a vein or the like for return (or access) (column 7 lines 18-19). The device is ordinarily in the state shown in FIG. 4, wherein flow between connector 108 and port 104 is blocked by the interruption of passages 112a and 112c by pistons 116 and 114 (note that piston 114 is mislabeled in FIG. 4). Similarly, flow between connector 110 and port 106 is blocked by the interruption of similar (but unshown) passages by the pistons. When the pistons 114 and 116 are lowered as in FIG. 6 by introduction of needle 120 into port 104 and introduction of needle 122 into port 106, passages 112b and 112d align with passages 112a and 112c to allow flow between connector 108 and port 104, and (unshown) passages are similarly opened between connector 110 and port 106 (column 7 line 45 onward). Thus, dislodgement of either needle 120/122 prevents access flow between connector 108 and port 104, and between connector 110 and port 106 (column 8 lines 13-19).



Independent claim 1 has been amended to incorporate its dependent claim 17 (which is now canceled), and is submitted to be both novel and unobvious in view of the references of record, since it is not seen how these references could be used to devise a valve wherein the location of the piston is independent of the pressure on the downstream side of the valve. In *Drevet et al.*, a major portion of the head of the piston 14 is exposed to the pressure in the downstream side 13 (see portion shown in fluid passageway 11 in FIG. 1 above – above the end of the lead line extending from reference number 11). As a result, the piston will plainly be affected by this pressure. This is evident from column 5 line 24 onward in *Drevet et al.*, discussing the behavior of the shunt at various upstream and downstream pressures, in particular, discussing downstream side 13 pressures ranging between -300mm to about 0mm. Turning then to *Burbank et al.*, the locations of pistons 114 and 116 are independent of the pressures on their downstream sides, but it does not seem possible to incorporate this feature into *Drevet et al.*. This is particularly true in view of the fact that *Burbank et al.* needs *manual actuation* – insertion of the needles – to actuate the pistons, and such a manual activation feature cannot reasonably be provided in a bodily fluid shunt such as *Drevet et al.*'s and still yield a practically usable shunt (since as a practical matter, a user/patient can hardly be expected to reliably manually actuate their shunt). In any event, it simply isn't seen how *Drevet et al.* could be adapted to have its piston act independently of downstream pressure. Since obviousness requires a reasonable expectation of success (MPEP 2143.02), and here it does not seem possible for an ordinarily skilled artisan to devise a way in which *Drevet et al.* can be modified to have its piston location be independent of the pressure on the downstream side of the valve, the invention of claim 1 cannot properly be deemed obvious.

It is also notable that even if one *could* devise a way in which *Drevet et al.* could be modified to meet claim 1, there does not appear to be any apparent reason or benefit to make such a modification, given that *Drevet* claims to address the issue of downstream pressures affecting desired valve actuation (see column 5 line 56 onward, particularly to column 6 line 17). Since “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” (MPEP 2141), and here there is no apparent reason to make the asserted modification, this is another reason why the invention of claim 1 cannot properly be deemed obvious.

The foregoing reasoning also applies to *independent claim 58*, which also recites that the location of the piston is independent of the pressure on the downstream side.

The claims dependent from claim 1 (claims 2-6, 8-16, 18-21, 72-75) and from claim 58 (claims 60-71) are submitted to be allowable for at least the same reasons as their parent claims. Of these, it is noted that the Office Action does not explain why claims 8-10 and 65-67 are believed to be obvious, and thus the rejections of these claims should be withdrawn because no proper case of *prima facie* obviousness has been made (MPEP 2142): the aforementioned “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” (MPEP 2141) is absent.

4. Rejection of Claims 72-77 under 35 USC §103(a) in view of U.S. Patent 5,643,195 to Drevet et al., U.S. Patent 6,565,525 to Burbank et al., and U.S. Patent 6,379,340 to Zinger

Kindly reconsider and withdraw these rejections. U.S. Patent 6,379,340 to Zinger *et al.* shows a valve allowing fluid drugs to be antiseptically withdrawn from a vessel (column 1 line 64 onward), wherein a port allows access by a needle or a cannula/tube, and a valve can be rotated to a position from which fluid can be withdrawn from the port, or to a position at which the valve does not allow fluid to transfer from the vessel to the port. Looking to FIGS. 2-3 as an example, drug may be dispensed from port 13, or from port 12 via insertion of a syringe 32 (column 4 lines 54-59). In FIG. 3, rotation of port 12 about the fluid conduit member 24 allows fluid drug from the interior of vial 28 to be directed to syringe 32 when port 12 and opening 14' are aligned with L-shaped passage 23/23', or to port 13 when port 13 and opening 16' are aligned with L-shaped passage 23/23' (column 5 line 4 onward). Also looking to FIG. 4, a semicircular passage 25 (shown adjacent opening 16' in FIG. 3) may be rotated between opening 16' and opening 14' to allow fluid to be transmitted between ports 12 and 13 (column 5 lines 17-25).

Initially, as regards the use of MPEP 2144.06 as a rationale for the rejection, it must be kept in mind that this section cautions:

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents.

Here, the equivalency does *not* seem to be recognized in the art, nor is *Zinger et al.* (nor U.S. Patent 5,540,668 to *Wilson et al.*) truly a functional or mechanical equivalent to *Drevet et al.* (or *Burbank et al.*):

- *Drevet et al.* automatically “switches” flow between input and output ports on or off depending on pressure relations between input and output (and valve motion is linear).
- *Burbank et al.* manually “switches” flow between input and output ports on or off depending on the operator’s preference, by the operator’s insertion of needles (and valve motion is linear).
- *Zinger et al.* (and *Wilson et al.*) are basically rotational stopcocks which *manually* switch flow from an input *to different outputs* depending on the operator’s preference, with valve motion being rotational.

This is not a matter of the simple substitution of one structure for an art-recognized equivalent. There are significant structural and functional differences such that one component / concept cannot readily be “swapped” for the other. Thus, the rationale for the rejection is erroneous.

Further, as explained in MPEP 2142:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

We submit that if this process is followed, with the claimed invention being placed out of mind and the prior art being objectively considered from the standpoint of an ordinary artisan, it cannot fairly be said that the ordinary artisan would contemplate or consider the claimed invention in view of *Zinger et al.*, particularly starting from *Drevet et al.* and *Burbank et al.* Considering that *Drevet et al.* and *Burbank et al.* operate on the basis of linear motion, and *Zinger et al.* is in essence little more than a rotating stopcock, it is simply not seen how one *could* incorporate features of *Zinger et al.* into the *Drevet / Burbank* combination, much less why one *would* truly and objectively consider doing

so. Kindly consider: again placing the claimed invention out of mind to avoid hindsight, how does one adapt *Drevet* to accommodate the allegedly “equivalent” rotating arrangement of *Zinger*? Or, considered differently, how could one having no knowledge of the invention truly devise a shunt having the characteristics of claims 72-75, *while also* having the recited features of parent claim 1?

In summary, we submit that when the references of record are fully and fairly considered for all they show or suggest to an ordinary artisan, it is seen that an ordinary artisan would not in fact consider an invention as recited in claims 72-75. Kindly withdraw these rejections.

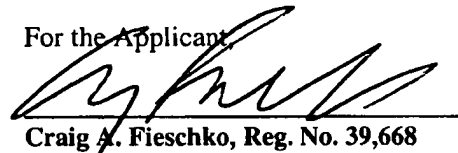
5. New Claims 72-77

These claims are submitted to be allowable because no art of record discloses or suggests a rotating piston, and/or a piston which rides in a curved path along a guide wall wherein the drain port is defined, and such arrangements are not believed to be in any way evident or foreseeable in view of the state of the art and the level of ordinary skill therein.

6. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant



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